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In the specification

A. Page 5, paragraph 2 is amended.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a transdermal preparation that can contain a high concentration of a hydrophilic or salt form drug in adhesive, and that shows increased skin permeation of drug, and that allows improved drug stability within the adhesive layer. More specifically, the present invention relates to a transdermal preparation **having an adhesive layer** comprising a drug to be absorbed through the skin and an adhesive that can contain the drug, wherein the drug is hydrophilic or a salt form, and the adhesive is an acrylic polymer having a poly(ethylene oxide) [called poly(ethylene glycol) in the case where the molecular weight is below 10,000] or poly(ethylene oxide) monomethyl ether side chain.

B. Page 7, the paragraph bridging page 8 is amended:

As a hydrophilic or salt form drug that can be incorporated into the transdermal preparation of the present invention, **examples include, but are not limited to:** sodium, potassium [or] **and** diethylammonium salts of diclofenac, amfenac, aceclofenac [or] **and** alclofenac; ketorolac tromethamine; hydrochloride, phosphate [or] **and** methanesulfonate salts of eperisone [or] **and** tolperisone; oxybutynin chloride; hydrochloride, [hydrobromate] **hydrobromide**, fumarate, succinate [or] **and** tartrate salts of diphenhydramine, ketotifen, doxylamine, promethazine and trimeprazine; hydrochloride [or] **and** sulfate salts of tulobuterol, clenbuterol, procaterol [or] **and** terbutaline; acetate, succinate, valerate [or] **and** disodium phosphate salts of hydrocortisone, dexamethasone [or] **and** betamethasone; and hydrochloride salts of ondansetron, granisetron [or] **and** ramosetron [can be enumerated, but not limited to them].

In the claims

Claims 1, 3-8, 10-15 and 17 are amended.

1. (twice amended) A transdermal preparation **having an adhesive layer** comprising a drug to be delivered through skin and an adhesive, wherein the drug is hydrophilic or in a salt form and the adhesive has a poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether side chain.

3. (twice amended) The transdermal preparation according to claim 1, wherein the amount of drug in the preparation is in a range of 1-50% by weight, based on the total weight of the [preparation] **adhesive layer**.

4. (twice amended) The transdermal preparation according to claim 1, wherein the molecular weight of the poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether is in a range of 100-30000, and wherein the amount of poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether in the [preparation] **adhesive** is in the range of 0.01-50% by weight based on the total weight of the [preparation] **adhesive**.

5. (twice amended) The transdermal preparation according to claim 4, wherein the molecular weight of the poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether is in a range of 400-5000, and wherein the amount of poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether in the [preparation] **adhesive** is in a range of 0.05-30 % by weight based on the total weight of the [preparation] **adhesive**.

6. (twice amended) The transdermal preparation according to claim 1, wherein the drug is selected from a group consisting of sodium, potassium and diethylammonium salts of diclofenac, amfenac, aceclofenac and alclofenac; ketorolac tromethamine; hydrochloride, phosphate and methanesulfonate salts of eperisone and tolperisone; oxybutynin chloride; hydrochloride, [hydrobromate] **hydrobromide**, fumarate, succinate and tartrate salts of

diphenhydramine, ketotifen, doxylamine, promethazine and trimeprazine; hydrochloride and sulfate salts of tulobuterol, clenbuterol, procaterol and terbutaline; acetate, succinate, valerate and disodium phosphate salts of hydrocortisone, dexamethasone and betamethasone; and hydrochloride salts of ondansetron, granisetron and ramosetron.

7. (twice amended) The transdermal preparation according to claim 2, wherein the solubilizer comprises at least one component selected from a group consisting of ethanol, isopropanol, poly(ethylene glycol), ethoxydiglycol, distilled water, propylene glycol, glycerin and dimethylsulfoxide, and wherein the amount of solubilizer in the [preparation] **adhesive layer** is in a range of 0.5-50% by weight based on the total weight of the [preparation] **adhesive layer**.

8. (twice amended) The transdermal preparation according to claim 2, wherein the skin permeation enhancer comprises at least one component selected from a group consisting of higher fatty acids; higher alcohols; higher fatty acid esters; fatty acid esters; fatty acid ethers of poly(ethylene glycol); fatty acid esters of poly(ethylene glycol); fatty acid ethers of propylene glycol; fatty acid esters of propylene glycol; sorbitan fatty acid esters; poly(ethylene glycol) sorbitan fatty acid esters; terpenes; sulfoxides; pyrrolidones; amides; and *N*-hydroxy methyl lactate, sorbitol, urea, squalene, olive oil, mineral oil and its derivative, and wherein the amount of skin permeation enhancer in the [preparation] **adhesive layer** is in a range of 0.5-50% by weight based on the total weight of the [preparation] **adhesive layer**.

10. (twice amended) The transdermal preparation according to claim 7, wherein the amount of the solubilizer and of the skin permeation enhancer in the [preparation] **adhesive layer** are each in a range of 1-30% by weight, based on the total weight of the [preparation] **adhesive layer**.

11. (once amended) The transdermal preparation according to claim 2, wherein the amount of drug is in a range of 1-50% by weight, based on the total weight of the [preparation] **adhesive layer**.

12. (once amended) The transdermal preparation according to claim 2, wherein the molecular weight of the poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether is in a range of 100-30000, and the amount of poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether is in the range of 0.01-50% by weight based on the total weight of the [preparation] **adhesive**.

13. (once amended) The transdermal preparation according to claim 2, wherein the drug is selected from a group consisting of sodium, potassium and diethylammonium salts of diclofenac, amfenac, aceclofenac and alclofenac; ketorolac tromethamine; hydrochloride, phosphate and methanesulfonate salts of eperisone and tolperisone; oxybutynin chloride; hydrochloride, [hydrobromate] **hydrobromide**, fumarate, succinate and tartrate salts of diphenhydramine, ketotifen, doxylamine, promethazine and trimeprazine; hydrochloride and sulfate salts of tulobuterol, clenbuterol, procaterol and terbutaline; acetate, succinate, valerate and disodium phosphate salts of hydrocortisone, dexamethasone and betamethasone; and hydrochloride salts of ondansetron, granisetron and ramosetron.

14. (once amended) The transdermal preparation according to claim 8, wherein the amount of the solubilizer and of the skin permeation enhancer in the [preparation] **adhesive layer** are each in a range of 1-30% by weight, based on the total weight of the [preparation] **adhesive layer**.

15. (once amended) The transdermal preparation according to claim 9, wherein the amount of the solubilizer and of the skin permeation enhancer in the [preparation] **adhesive layer** are each in a range of 1-30% by weight, based on the total weight of the [preparation] **adhesive layer**.

17. (once amended) A pharmaceutical dosage form for transdermal delivery of a hydrophilic or salt form drug, the dosage form comprising an amount of the drug [and] **in** an acrylic polymer adhesive, wherein the acrylic polymer has a poly(ethylene oxide) or poly(ethylene oxide) monomethyl ether side chain.

Remarks

The specification is amended to correct typographic errors and the claims are amended to clarify the invention; no new matter is added.

Support for a transdermal preparation having an adhesive layer comprising a drug and an adhesive as defined, is found at:

page 5, line 9-11 and page 31, lines 3-5 ("that can contain high concentration of hydrophilic or salt form drug in adhesive ... and allows improved drug stability within the adhesive layer.");

page 5, lines 17-20 ("... to increase drug concentration within the adhesive layer. ... to improve skin permeation of drug within the adhesive layer.")

In the claims, "preparation" is replaced by "adhesive" or "adhesive layer". Support for these amendments is found throughout the specification and in original claims 1-10.

Applicants respectfully request examination and consideration of claims 1-17.

Respectfully submitted,

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